

REMARKS/ARGUMENTS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the above amendments and following remarks, which place the application into condition for allowance.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1-33 are pending in this application and are rejected in the Office Action mailed December 26, 2006. Claims 1-12 and 31-33 have been withdrawn from consideration. Claims 13-30 are rejected in the Office Action mailed on December 26, 2006. By this Amendment, claims 13, 19, 24, and 25 are amended as detailed above. Support for these amendments can be found throughout the Specification as originally filed, see for example Figs. 9 and 12 and the corresponding detailed description for each figure found on pages 9 and 10, respectively. It is believed that no new subject matter is added as a result of the amendments to the claims.

Initially, Applicants' attorneys would like to thank the Examiner for acknowledging the claim for priority based on Italian Application VR 2002A000094, filed September 25, 2002. The Examiner has noted that a certified copy of the priority document is required and has not been provided. Applicants' attorneys respectfully submit that a certified copy was provided to the Patent and Trademark Office on September 15, 2003, as indicated on the USPTO's public PAIR web site. The Examiner is respectfully requested to acknowledge that the certified copy requirement has been satisfied. A copy of the priority document printed from public PAIR is included

II. THE REJECTIONS UNDER 35 U.S.C. § 112

On page 3 of the Office Action, claims 13-30 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically,

the Examiner asserts that independent claims 13 and 25 do not provide a correlation between the position of the mask and the inflatable pad to the compress. Additionally, claim 30 is rejected under § 112, first paragraph, for allegedly failing to describe how the active ingredients in the compress will be directed to an area of inflammation.

On page 4 of the Office Action, claims 13-30 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner alleges claims 13-30 are incomplete for omitting the essential element of the relation of the compress with the inflatable pad or the facial mask. Further, the Examiner rejects claim 19, alleging the term “pump” does not set forth the metes and bounds of the claim. Lastly, claim 24 is rejected because it recites that the mask comprises plastic while the disclosure allegedly discloses a mask made of plastic.

As to the § 112, first paragraph rejections, amended claim 13, as outlined above, recites:

A device comprising a facial mask, an inflatable elastic pad affixed to the facial mask and a compress *affixed to said inflatable elastic pad*, said compress comprising a revulsive or cress having an active ingredient, wherein the device promotes the absorption of the active ingredient to bones underlying mucous membranes in a sinus of a person in need thereof.

(emphasis added). Similarly, amended claim 25, as outlined above, recites:

A method of treating sinusitis comprising the step of securing a device to a person's head, the device comprising a facial mask, an inflatable elastic pad affixed to the facial mask and a compress *affixed to said inflatable elastic pad*, said compress comprising a revulsive or cress having an active ingredient, wherein the device promotes the absorption of the active ingredient to bones underlying mucous membranes in a sinus of a person in need thereof.

(emphasis added). Applicants' attorneys respectfully submit that revised claims 13 and 25 provide an adequate correlation between the position of the mask and the inflatable pad to the compress. Additionally, originally filed Fig. 12, and the associated detailed description found on page 10, lines 3-17 of the instant application, clearly show and describe the relationship between the position of the mask, the inflatable pad, and the compress. Thus, Applicants' attorneys respectfully submit that the relationship between the compress and the mask and inflatable pad is clearly defined and therefore respectfully request that the § 112, first paragraph rejections of claims 13 and 25 be withdrawn.

Concerning the Examiner's rejection of claim 30 for allegedly failing to describe how the active ingredients in the compress will be directed to an area of inflammation, Applicants' attorneys respectfully submit that because the present invention comprises a facial mask used in the treatment of illnesses of the paranasal sinuses and of the trigeminal nerve, it would be clear to one of ordinary skill in the art that the instant invention is worn on the face. In addition, the Specification discloses, at least on page 6, that the mask is fitted to the upper part or the lower part of the face and secured to the wearer's head. Additionally, at least on page 7 of the Specification, it is recited that the compress comprises a revulsive or cress containing an active ingredient. It is further recited that the compress is designed to yield the active ingredient in the revulsive or cress when pressure is applied to the compress. Further, in the Specification, for example on pages 7 and 8, the results of applying pressure to the compress through the compression chamber are outlined as

- a) squeezing the compress to force out the active ingredient (allyl isothiocyanate);
- b) opening skin pores to which pressure is applied; and
- c) forcing the active ingredient through the opened skin pores in the direction of the damaged or inflamed area.

Therefore, Applicants' attorneys respectfully submit that the Specification does describe how the active ingredients will be directed in the direction of the inflammation. Thus, Applicants' attorneys respectfully request that the § 112, first paragraph, rejection of claim 30 be withdrawn.

The Office Action also rejects claims 13-30 under § 112, second paragraph, as allegedly being indefinite for omitting the relation of the compress with the inflatable pad or facial mask. For the reasons cited above, Applicants' attorneys respectfully submit that the Specification as originally filed adequately describes the relation between the compress and the mask and inflatable pad and thus complies with § 112, second paragraph. Additionally the Examiner rejects claim 19 for allegedly failing to set forth the metes and bounds of the claimed pump. While Applicants' attorneys do not agree with the Examiner's assertions, in order to advance prosecution, claim 19 has been amended as outlined above to recite a "manual" pump. Support for this amendment can be found, at least, on page 7, line 10 of the Specification and in Fig. 9, and the associated detailed description on page 9 of the Specification. Lastly, the Examiner rejects claim 24 for reciting that the mask comprises plastic while allegedly disclosing the mask is made of plastic. While Applicants' attorneys do not agree with the Examiner's assertions, in order to advance prosecution, claim 24 has been amended as outlined above, to recite that the mask is "made of plastic." Support for this amendment can be found at least on page 6, lines 26-27 of the Specification as originally filed. Consequently, Applicants' attorneys respectfully requests that the § 112, second paragraph, rejections of claims 13-30 be withdrawn.

III. THE REJECTIONS UNDER 35 U.S.C. § 103(a)

On page 6 of the Office Action, the Examiner rejects claims 13, 15-25, and 27-30 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 2,262,711 to Ludwin ("Ludwin") in view of U.S. Patent No. 4,193,401 to Marinello ("Marinello"). In addition, the Examiner rejects claims 14 and 26 under § 103(a) as allegedly being unpatentable over Ludwin in view of Marinello, and further in view of U.S. Patent No. 5,248,504 to Friedman ("Friedman"). The rejections are traversed for at least the following reasons.

As recited in revised independent claim 13, the instant invention is directed to a facial mask comprising, *inter alia*, an inflatable pad attached to a compress containing a revulsive or a cress "wherein the device promotes the absorption of the active ingredient to bones underlying mucous membranes in a sinus of a person in need thereof." As disclosed at least on page 4, lines 15-19 of the instant Specification, the active ingredient of the present invention penetrates the skin of the wearer until the inflammation or the damaged area and the bones underlying the mucous membranes are reached. As further disclosed on page 6, lines 30-32 of the instant Specification, the mask of the instant invention is adapted to freely accommodate normal respiratory functions through the nostrils and mouth of the wearer. Based on the instant disclosure, one of ordinary skill in the art would understand that the instant invention is not configured to introduce any substance to the respiratory system.

In contrast, Ludwin relates to a nebulizer comprising a mask adapted to deliver volatized medicaments to the wearer. Specifically, Ludwin describes a mask adapted to cover the nose, or nose and mouth. By definition, a nebulizer delivers a fine mist of medicated vapors into the respiratory system. Ludwin also describes an air pressurized system adapted to urge the volatized medicaments into the small pores of the sinus tract by way of the respiratory system.

Thus, Ludwin's invention makes the nose and/or mouth of the wearer unavailable for normal respiratory function while introducing volatilized medicaments to the respiratory system of the wearer. Ludwin fails to teach or suggest the absorption of any medicament to bones underlying mucous membranes in the sinuses of a person in need thereof.

Marinello fails to cure the deficiencies of Ludwin. Marinello is directed to an apparatus applicable to the external part of the orbital cavity to introduce medicaments for the cure of internal injuries, wounds, or inflammation to the ocular organs and the central nervous system. *See e.g. Marinello*, col. 3, lines 35-43. Marinello fails to teach or suggest an apparatus that would be appropriate or effective for the introduction of medicaments to any other tissue. Specifically, there is no suggestion that such an apparatus would be successful in delivering active ingredients through mucous membranes to the underlying bones in the sinuses. As presently understood, Marinello is directed specifically to the treatment of the ocular organs and the central nervous system which does not suggest absorption into bone.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings either in the references themselves or in the general knowledge available to one of ordinary skill in the art; second, there must be a reasonable expectation of success; third, the prior art reference or references must teach or suggest all the claim limitations. *M.P.E.P.* § 2143; *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); *In re Laskowski*, 871 F.2d 115 (Fed. Cir. 1989); *In re Merck & Co., Inc.*, 800 F.2d 1091 (Fed. Cir. 1986); and *In re Royka*, 490 F.2d 981 (CCPA 1974). Therefore, because the combination of Ludwin and Marinello at least fails to teach, disclose or suggest all of the instant claim limitations, specifically the absorption of the active ingredients to bones underlying mucous membranes in a sinus of the wearer, the Section

103 rejections must fail as a matter of law. Accordingly, Applicants' attorneys respectfully request that the Section 103 rejections be withdrawn.

For at least the foregoing reasons, it is believed that revised independent claim 13 patentably distinguish over the relied upon portions of Ludwin and Marinello, either alone or in combination, and is therefore allowable. Revised independent claim 825 is similar or somewhat similar in scope to revised independent claim 13 and is therefore allowable for similar or somewhat similar reasons to those for claim 13. Further, claims 14-24, which depend from claim 13, and claims 26-30 which depend from claim 25, are allowable as well.

Statements appearing above with respect to the disclosures in the cited references represent the present opinions of the Applicants' undersigned attorney and, in the event that the Examiner disagrees with any such opinions, it is respectfully requested that the Examiner specifically indicate those portions of the respective reference providing the basis for a contrary view.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are patentable over the prior art, and an early and favorable consideration thereof is solicited.

Please charge any fees incurred by reason of this response and not paid herewith to Deposit Account No. 50-0320.

Respectfully submitted,
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